Testimony of

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on behalf of the

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Chairman Deal, Congressman Brown, and distinguished Sub-committee members, I am Dr. Bruce Perry, a family physician and geriatrician and Medical Director of The Southeast Permanente Medical Group, which together with Kaiser Foundation Health Plan of Georgia make up Kaiser Permanente's Georgia Region. I also serve as Chairman of the Executive Committee of the Permanente Federation, the umbrella organization that coordinates national activities of the eight Permanente Medical Groups. I appreciate the opportunity to testify here today on the important subject of access to generic drug therapies. Timely access to high quality generic drugs is central to Kaiser Permanente's efforts to provide high quality and affordable prescription drug benefits.

I am testifying today on behalf of the national Kaiser Permanente Medical Care Program. Kaiser Permanente is the nation's largest integrated health care delivery system. We provide comprehensive health care services to more than 8.4 million members in our 8 regions, located in 9 states[1] and the District of Columbia. In each Region, the nonprofit Kaiser Foundation Health Plan enters into a mutually exclusive arrangement with an independent Permanente Medical Group to provide all medical services required by Health Plan members.

In our organization, virtually all pharmacy services are provided directly in Kaiser Permanente facilities by Health Plan employed pharmacists. This year, Permanente physicians will prescribe and Kaiser pharmacists will dispense more than $3 billion worth of prescription drugs. Our physicians and pharmacists make their best efforts to ensure that our members receive the highest possible quality and most cost-effective pharmaceutical care based on the best and most current available clinical evidence. This is supported by a strong culture of cooperation and collaboration between our medical groups and our pharmacy program.

It is this very close partnership between the pharmacy operations team of our Health Plan and the physicians of the Permanente Medical Groups that allows Kaiser Permanente to experience very high levels of use of generic drugs. While the Generic Pharmaceutical Association reports that 53 percent of prescriptions in the United States are written for generic drugs, approximately 70 percent of all prescriptions written by Permanente physicians nationally are for generic drugs. More than $250 billion was spent by or on behalf of US patients in 2004 for prescription drugs. There is no question that improved generic prescribing by US physicians has the potential to save many billions of dollars – money that can be spent on other health care services or newer drugs, or simply saved, slowing the growth of overall health care spending.

We expect that our pharmaceutical costs will increase annually in excess of the overall inflation rate. How much more than the inflation rate is the real question. We acknowledge that increased pharmaceutical utilization can in well-defined instances improve health and/or reduce spending on hospital and medical services that drugs make unnecessary. Overall, however, it is true that rising drug spending increases overall health care costs. Capturing the value of prescription drugs, and avoiding waste, is enhanced by the effective use of generic drugs.

[1] California, Colorado, Georgia, Hawaii, Maryland, Ohio, Oregon, Virginia and Washington

Determining the Preferred Drugs for Kaiser Permanente Members

At Kaiser Permanente, we take very seriously our obligation to deliver the highest quality care to our members. As with virtually all other health plans, each Kaiser Permanente region establishes a formulary that includes a list of drugs that are preferred as first-line therapies. The formulary is established by a regional pharmaceutics and therapeutics (P&T) committee.

Our P&T committees are comprised of Permanente physicians from a broad range of medical disciplines and the regional pharmacy services director. When a new drug becomes available to treat a particular condition, or when a review of existing drug therapies is undertaken, the P&T committee is commonly aided by physicians with expertise in the appropriate specialty.

When a new blood pressure medicine becomes available, for example, a panel of cardiologists and internists will make recommendations to the P&T committee. Their recommendations will reflect the latest information on all drugs in the therapeutic class as presented in a monograph prepared for the P& T committee by our pharmacist-staffed drug information service. The drugs included on the preferred drugs lists are those that, first and foremost, evidence indicates are clinically superior to the other drugs in the therapeutic class. If the preferred drug is available as a generic, the generic version will virtually always be the preferred drug on the formulary. Along with formulary-consistent prescribing by Permanente physicians, this explains in large part why Kaiser Permanente has been so successful in using generic drugs.

Opportunities Presented by High Quality Generic Drugs

I would like to discuss three examples that illustrate how Kaiser Permanente uses generics to match clinical excellence with cost savings opportunities when they are available in a class that contains many drugs. While it is true that drugs that recently received FDA approval sometimes provide additional value for patients in terms of reduced side effects or greater efficacy, it is difficult to measure that value because only very rarely do brand name pharmaceutical manufacturers conduct head-to-head studies to assess whether newer drugs really are better than other available drugs. Independent head-to-head comparative research is also rare. However, one general observation can be made – many, if not most, patients can be successfully treated with available generic drugs. If these drugs fail to achieve the desired therapeutic outcome, a newer drug can be prescribed. This is particularly true when what was originally a breakthrough drug becomes available as a generic drug, and the follow-on alternatives are still under patent.

Antidepressants

A good example is Prozac and follow-on antidepressants known as selective serotonin reuptake inhibitors or SSRIs. When Prozac, now generically available as fluoxetine, first came to market in the late 1980s, it was generally accepted as a breakthrough over the older tricyclic antidepressants. While probably no more effective than the older, existing drugs, the much less onerous side effects of Prozac meant that patients were much better able to tolerate Prozac and continue therapy. As a result, this became the drug of choice for a proportionately large number of patients with clinically diagnosed moderate depression.

In the years that followed, competitors in the class of SSRIs, Paxil (paroxetine), Zoloft (sertraline), Celexa (citalopram), and line extensions and follow-on versions of all of these (weekly Prozac, extended release Paxil, Lexapro (escitalopram)) became available, providing a panoply of choices for clinicians in a pharmacological area where the first treatment, whatever is selected, may not be successful. It is important to note that, while SSRIs have somewhat different side effects profiles, none of these drugs appear to have meaningfully different performance as the first drug in the class prescribed to a patient. In other words, no one really knows whether a patient will succeed on the first choice, no matter what the first choice is.

Today, high quality generic versions for Prozac, Paxil and Celexa are available. As a result, it is possible to start virtually all patients (except for those with a known sensitivity to or a side effect from a particular drug) on any one of the generic alternatives before attempting therapy on drugs that are still under patent. An appropriate strategy like this, which is implemented in all Kaiser Permanente regions, enables Permanente physicians to offer our patients both high quality therapy and lower copayments (generic copayments are generally lower than those for brand name drugs). By reserving the patented alternatives for those patients who truly need them, we are able to keep drug costs, and employer and individual premiums that are directly related to those costs, down.

We estimate that our regional "Fluoxetine First" programs, which are approved by all of our Regional chiefs of psychiatry, save Kaiser Permanente members over $100 million annually in drug costs nationally, compared to broader U.S. prescribing patterns. If all U.S. prescribing of these drugs for new patients requiring antidepressants matched that of Permanente physicians, there would be savings of well into the billions of dollars annually with no reduction in clinical quality.

Cox-2 Inhibitors and other Nonsteroidal Anti-inflammatory Drugs

Cox-2 inhibitors (such as Celebrex, Vioxx and Bextra) represent a type of non-steroidal anti-inflammatory drug (NSAID) that have been used to treat the pain and inflammation that comes with various forms of arthritis. It was believed that Cox-2 inhibitors would provide an advantage over older NSAIDs (like ibuprofen and naproxen) because they were presumed to cause significant gastrointestinal side effects, which can

include bleeding from gastrointestinal ulcers. They have never been considered superior pain relievers, although heavy promotion of these drugs may have led many patients to believe they are. We now know that high doses of these drugs represent a significant cardiovascular risk for patients and as of today, two of the three Cox-2s, Vioxx and Bextra, have been removed from the market. Caution dictates that physicians should reserve the remaining Cox-2 inhibitor, Celebrex, for those patients who fail on traditional NSAID therapy and do not have significant cardiovascular risk factors.

Even before the early hints of serious cardiovascular risk were confirmed and widely accepted by the medical community, work done by scientists at Stanford University showed that the potential gastrointestinal safety benefit of Cox-2 inhibitors was largely limited to patients who were at high risk of serious gastrointestinal bleeding from traditional NSAIDs. This was important because they found that fewer than five percent of patients are actually at high risk of serious gastrointestinal side effects.

In a very practical response to these data, the same scientists developed a scoring tool to apply to patients who were candidates for NSAIDs to determine their risk levels. Kaiser Permanente, with the enthusiastic support of our Regional chiefs of rheumatology and internal medicine, adopted this scoring tool to provide physicians with simple, automated methods to know the risk levels of the patients they were seeing. Once this scoring tool was implemented, Permanente physicians prescribed Cox-2 inhibitors for Kaiser members less than five percent of the time when NSAID therapy was necessary. Until the recent withdrawal of the two Cox-2s, among the rest of the US population, these drugs were being prescribed approximately 50 percent of the time. The lack of good independent, credible information for physicians about the limited clinical role for these medicines combined with ubiquitous promotion to patients and physicians meant that millions more patients than necessary were prescribed them, and billions of dollars in needless drug expenditures resulted.

We estimate that in 2004 alone, if U.S. use of the three Cox-2s compared to traditional NSAIDs had matched that of Permanente physicians, U.S. consumers and businesses paying for prescription drugs would have saved over $4 billion dollars, or almost 2 percent of <u>all</u> U.S. drug spending. Here is a great example where promoting the use of high-quality generic drugs can be not only significantly less costly, but safer.

<u>Cholesterol-lowering Statins</u>

A few years ago, the *Wall Street Journal* reported on Kaiser Permanente's use of generic lovastatin (Mevacor) as the first line cholesterol lowering drug for our members. While lovastatin is not the most potent statin on the market, through appropriate dosing a majority of patients can readily achieve their target cholesterol levels. Members who have a clinical need for a more potent statin have easy access to them. An astonishing fact is that Kaiser Permanente physicians can treat six patients appropriately with lovastatin for the same cost as one patient on one of the still-patented alternatives. This program along with other steps taken by Kaiser Permanente to address cardiovascular disease has been so successful

that in Northern California, for example, it was recently determined that heart disease is no longer the leading cause of death among Kaiser Permanente members (cancer is), even though it remains the leading cause for non-Kaiser Permanente members in the San Francisco area and throughout the nation.

How Appropriate Generic Prescribing is Achieved

The value of generic drugs is maximized when programs are designed in a way that does not deny access to necessary but more expensive brand name prescription drugs. Our goal, instead, is to target the more expensive drugs to those patients who stand to benefit from whatever additional value newer drugs might provide, rather than simply defaulting automatically to the newest drug for all patients. This result is equally high quality, but far more cost effective use.

These programs work within Kaiser Permanente for several reasons.

- First and foremost, our physician clinical experts are intimately involved in the development and implementation of good drug use management initiatives. Permanente physicians have the confidence that their most expert colleagues are in agreement with the recommendations for drug use initiatives.

- Second, the Health Plan's clinical pharmacists are available for consultation and provide the latest information about alternative drug therapies. Kaiser Permanente invests significant resources to make sure that physicians have ready access to the best objective drug information that exists.

- Third, physicians delivering care to patients know that they will not be penalized for prescribing nonformulary or more expensive brand name drugs – they know that those drugs are readily available when necessary. Indeed, they know that some patients will need the newer drugs and receive them when needed.

- Finally, Permanente physicians know that savings resulting from their efforts will either lower member premiums or enable spending in other areas, whether subsidizing other, more expensive drugs, building new facilities or buying necessary medical equipment.

The Broader Challenge

If it is Kaiser Permanente's integrated nature, financial structure and close cooperation among physicians and pharmacists that leads to our high use of generic drugs, the question remains: what lessons learned in the group practice environment can be applied in less integrated settings?

It might not be possible for other types of health plans to achieve Kaiser Permanente's level of success in generic prescribing, but I believe that steps are already

being taken that can help realize savings through increased use of generic drugs. Physicians are clamoring for better, objective information about the comparative clinical effectiveness of prescription drugs. Thanks to the work of this Committee, the Medicare Modernization Act included provisions authorizing the Agency for Healthcare Research and Quality to initiate a research agenda on the comparative effectiveness of alternative therapies, including drugs for the same condition. For fiscal year 2005, Congress appropriated $15 million to fund this activity. While modest, it is an important first step, and we encourage members to support increased funding in future years. We strongly believe that increased support for this important research will result in exponentially greater savings in the future, as physicians see clinical evidence that guides their practices. I am confident that the research will show that generic drugs can be used safely and effectively more frequently than they are now.

We also believe that physician organizations, such as medical associations and specialty societies, need to take the lead in defining best practices. Much that is learned from multispecialty group practices like the Permanente Medical Groups and our colleagues in academic medicine and medical foundations is not effectively translated to the larger medical community. We think our colleagues in organized medicine can play an important role in expanding good drug use practices.

The new Medicare drug benefit also provides an opportunity to expand appropriate use of generics. The new drug benefit will provide important value for Medicare beneficiaries, but other than for low income persons, many beneficiaries will experience gaps in coverage. In this context, high-quality, affordable generics are critical to ensure that beneficiaries have access to the therapies they need. Simply stated, Medicare beneficiaries can have many more of their prescriptions covered under the current benefit design if generic medicines are appropriately prescribed. We are confident that CMS can and will work with physicians caring for Medicare beneficiaries in ways that will provide information about the relative value and clinical appropriateness of generic drugs.

Mr. Chairman, thank you for the invitation to testify here today. I would be happy to answer any questions you may have.